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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/571,783

03/14/2006

Nicolas Shan

05841041

8339

466 7590 09/06/2007

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EXAMINER

TREYGER, ILYA Y

ART UNIT

PAPER NUMBER

3709

MAIL DATE

DELIVERY MODE

09/06/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/571,783

Applicant(s)

SHAN ET AL.

Examiner

Ilya Y. Treyger

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application:
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 03/14/2006.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

### DETAILED ACTION

Claims 1-14 of US Application 10/571,783, filed 09/17/2004, are presented for examination.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leisner et al. (US 6,626,878) in view of Holtermann et al. (US 4,846,798).

1. In Re claim 1, Leisner discloses an Ostomy device connection which is intended to connect a collection pouch (1) to a fixing device which is intended to be adhesively-bonded to the skin of a user, the connection serving:

to transmit the weight of the collection pouch (1) to the fixing device,

to position the pouch (1) relative to the fixing device so that a hole (20) of the fixing device is in communication with a hole (21) of the collection pouch (1), and to provide sealing between the collection pouch (1) and the fixing device,

the connection comprising a first connection portion (2) which is fixedly joined to the fixing device and a second connection portion which is fixedly joined to the collection pouch (1),

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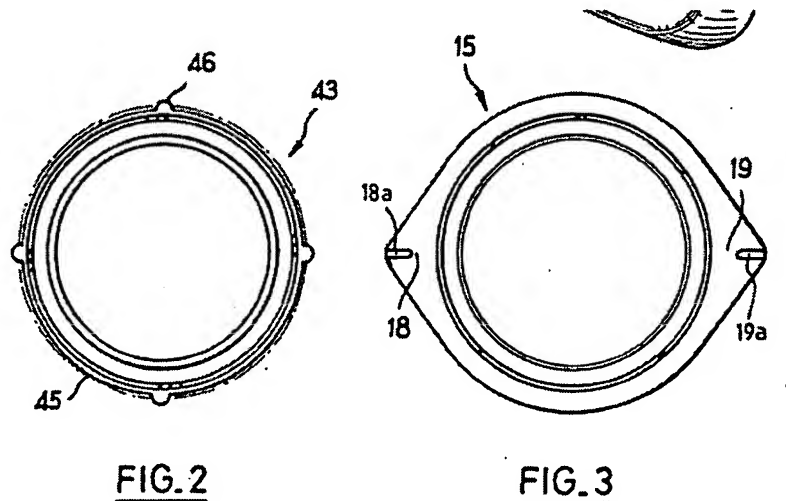
one of the connection portions having an adhesive surface which is covered before use by a removable protective sheet (11) and the other connection portion having an adhesion strip (8), so that the two connection portions can co-operate with each other by means of adhesive-bonding in a plane which is practically perpendicular relative to the axes of the holes of the pouch and the fixing device, and the transmission of the weight of the collection pouch (1) and the sealing between the fixing device and collection pouch (1) are provided by means of adhesive-bonding, the collection pouch (1) and the fixing device. The protective sheet (8) of the adhesive layer has the feature of being able to be removed from the adhesive surface (See Abstract, ln. 1-16; Col. 2, ln. 5, 13-16, 32-33, 39-43, 30-31, 36-37; Fig. 1 and 2).

Leisner does not expressly disclose the collection pouch and the fixing device comprising complementary fixing elements which are intended to limit the possibilities for relative displacement of the pouch and the fixing device so that the two connection portions have practically only one

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possible relative position when they are adjacent, this position corresponding to the alignment of the holes of the fixing device and the collection pouch.

Holtermann teaches that it is known to use complementary fixing elements (46, 19a) for collection pouch and a fixing device (See Fig. 2 and 3).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ostomy device connection of Leisner with the complementary fixing elements, as taught by Holtermann because such modification would increase the consumer benefits of the product.

2. In Re claim 10, Leisner discloses the connection characterized in that the portion having the adhesive surface is intended to be detached in one direction after use, and the configuration of this adhesive surface is such that the total length of the face for detaching by means of peeling, in a direction which is generally perpendicular relative to the detaching direction, is modulated so that it is substantially constant over the majority of the length of the portion having the adhesive surface in the detaching direction (See Col. 2, ln. 32-33; Col. 3, ln. 3-5).

Claims 2, 5, 7, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leisner et al. (US 6,626,878)/ Holtermann et al. (US 4,846,798) in view of Marcel H. Wagenknecht (US 5,167,661).

1. In Re claim 2, Leisner/ Holtermann disclose the claimed invention discussed above, but do not expressly disclose the connection characterized in that the complementary fixing elements form an articulation device which delimits a pivot axis remote from the holes of the fixing device and the collection pouch, the protective sheet being practically entirely at only one side of the pivot axis.

Wagenknecht teaches that it is known to use articulation device for locking of two pieces (See. Abstract, ln. 1-13).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ostomy device connection of Leisner/ Holtermann with the articulation device, as taught by Wagenknecht because such modification would improve the reliability of the complementary fixing elements.

2. In Re claim 5, Wagenknecht discloses the connection characterized in that the complementary fixing elements comprise a tongue (19) which is fixedly joined to a first portion of the connection and a curved member (46) which is fixedly joined to the other portion of the connection (See Fig. 2 and 3).

3. In Re claim 7, Wagenknecht discloses the connection characterized in that the complementary fixing elements comprise at least a first element (19) which is arranged on a first connection portion, and a plurality of second elements (46) which are arranged on the other connection portion and which have positions which are angularly spaced-apart around the hole of the corresponding connection portion, the first element being able to co-operate with any one of the second elements (See Fig. 2 and 3).

3. In Re claim 8, Leisner/ Holtermann/ Wagenknecht disclose the claimed invention discussed above except for connection characterized in that the portion which comprises the portion carrying the tongue (19) comprises a plurality of tongues having positions which are angularly spaced-apart around the hole thereof.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of tongues having positions, which are angularly spaced-apart around the hole, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art (**MPEP 2144.04 (VI-B)**). *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

4. In Re claim 11, Holtermann discloses the connection characterised in that the complementary fixing elements comprise at least a first element (19) which is arranged on a first connection portion, and a plurality of second elements (46) which are arranged on the other connection portion and which have positions which are angularly spaced-apart around the hole of



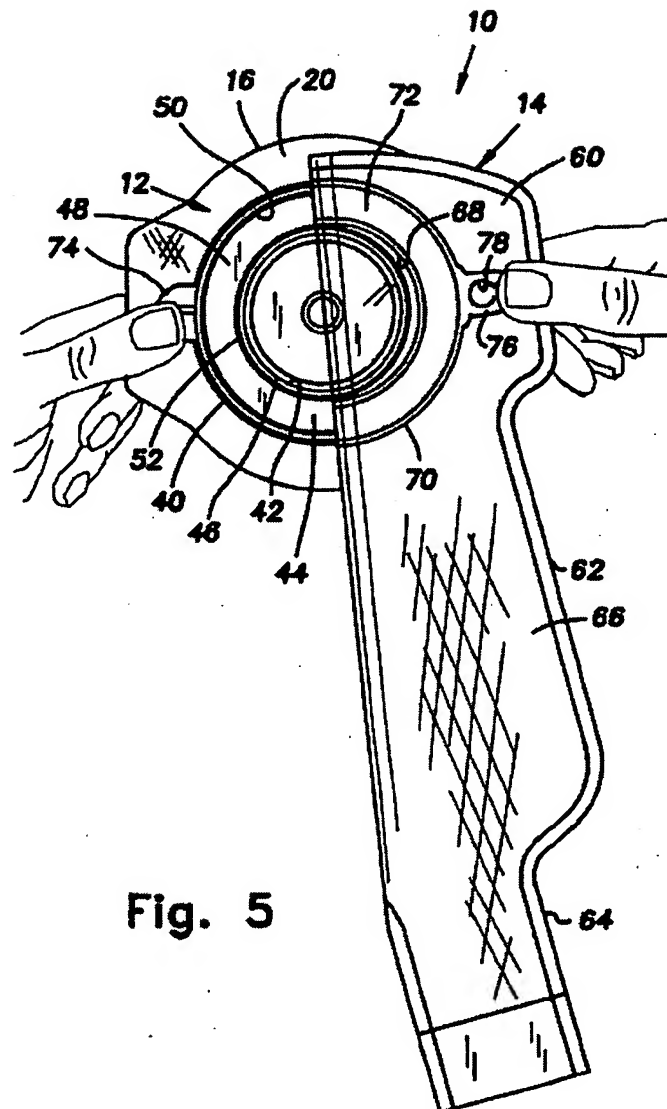
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the corresponding connection portion, the first element being able to co-operate with any one of the second elements (See Fig. 2 and 3).

Claims 3 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leisner et al. (US 6,626,878)/ Holtermann et al. (US 4,846,798)/ Marcel H. Wagenknecht (US 5,167,661), as applied to claim 2, in further view of Leonard Fenton (US 5,429,626).

1. In Re claim 3, Leisner/ Holtermann/ Wagenknecht disclose the claimed invention discussed above, but do not expressly disclose the connection characterized in that the complementary fixing elements comprise at least two push-buttons which are aligned along an axis.

Fenton teaches that it is known to supply the ostomy connection with two push-buttons (78, 74)(See Fig. 5).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ostomy device connection of Leisner/ Holtermann/ Wagenknecht two push-buttons, as taught by Fenton because such modification would increase the consumer benefits of the product.

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2. In Re claim 12, Holtermann discloses a connection characterised in that the complementary fixing elements comprise at least a first element (19) which is arranged on a first connection portion, and a plurality of second elements (46) which are arranged on the other connection portion and which have positions which are angularly spaced-apart around the hole of the corresponding connection portion, the first element being able to co-operate with any one of the second elements (See Fig. 2 and 3).

Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leisner et al. (US 6,626,878)/ Holtermann et al. (US 4,846,798)/ Marcel H. Wagenknecht (US 5,167,661), as applied to claim 2, in further view of Sheldon H. Lerman (US 4,338,937).

1. In Re claim 4, Leisner/ Holtermann/ Wagenknecht disclose the claimed invention discussed above, but do not expressly discuss the connection characterized in that the complementary fixing elements comprise two elements which are fixedly joined to the fixing device and the pouch, respectively, and which are able to provide mutual fixing by means of magnetic attraction.

Lerman teaches that it is known to supply ostomy connection with means of magnetic attractions (See Col. 2, ln. 65-66).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ostomy device connection of Leisner/ Holtermann/ Wagenknecht with means of magnetic attractions, as taught by Lerman because such modification would increase the fixation options of the product.

2. In Re claim 13, Holtermann discloses the connection characterized in that the complementary fixing elements comprise at least a first element (19) which is arranged on a first connection portion, and a plurality of second elements (46) which are arranged on the other connection portion and which have positions which are angularly spaced-apart around the hole of the corresponding connection portion, the first element being able to co-operate with any one of the second elements (See Fig. 2 and 3).

Claims 6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leisner et al. (US 6,626,878)/ Holtermann et al. (US 4,846,798)/ Marcel H. Wagenknecht (US 5,167,661), as applied to claim 2, in further view of Jones et al. (US 5,912,059).

1. In Re claim 6, Leisner / Holtermann/ Wagenknecht disclose the claimed invention discussed above, but do not expressly disclose the connection characterized in that the complementary fixing elements comprise shaped portions of hook and loop type fabric which are fixedly joined to each of the connection portions.

Jones teaches that it is known to use fasteners of the hook and loop type in ostomy connection devices (See Col. 5, ln. 50-51).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ostomy device connection of Leisner/ Holtermann/ Wagenknecht with fasteners of the hook and loop type, as taught by Jones because such modification would improve the fixation options of the product.

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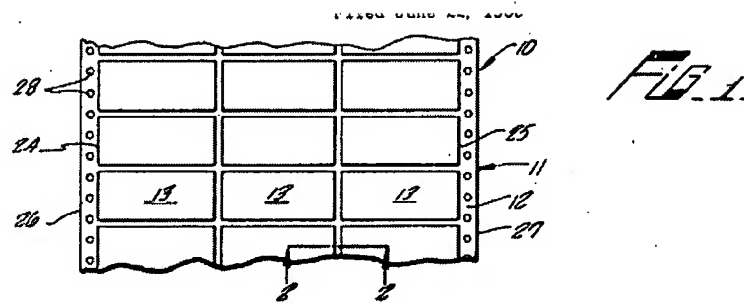
2. In Re claim 14, Holtermann discloses the connection characterised in that the complementary fixing elements comprise at least a first element (19) which is arranged on a first connection portion, and a plurality of second elements (46) which are arranged on the other connection portion and which have positions which are angularly spaced-apart around the hole of the corresponding connection portion, the first element being able to co-operate with any one of the second elements (See Fig. 2 and 3).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leisner et al. (US 6,626,878)/ Holtermann et al. (US 4,846,798), as applied to claim 1, in further view of E. A. SINGER (US 3,383,121).

Leisner/ Holtermann disclose the claimed invention discussed above, but do not expressly disclose the connection characterized in that the protective sheet of the adhesive layer comprises at least two portions which are folded in the form of a folder whose folds are adjacent on the adhesive surface so that this adhesive surface is completely covered and the flap which is not adhesively-bonded to the adhesive surface has a gripping lug which extends beyond the limits of the adhesive surface.

SINGER teaches that it is known to make protective sheet comprises at least two portion which are folded so that this adhesive surface is completely covered and the flap which is not adhesively-bonded to the adhesive surface has a gripping lug which extends beyond the limits of the adhesive surface (See Fig. 1).

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ostomy device connection of Leisner/ Holtermann with the protective sheet, as taught by SINGER because such modification would improve the consumer benefits of the product.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5843053 disclose a Ostomy coupling. US 6033390 disclose a Continent ostomy port. US 5520670 disclose a Self-aligning ostomy device. US 5312381 disclose an Ostomy pouch coupling having continuous helical threads. US 5257981 Ostomy appliance. US 4894058 disclose an Adhesive connecting rings for an ostomy device. US 4359051 disclose an Ostomy appliance closure.

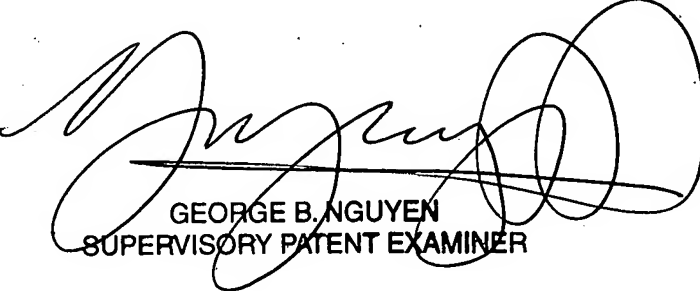
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ilya Y. Treyger whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Nguyen can be reached on 571-270-1431. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ilya Y. Treyger  
Examiner  
Art Unit 3709



GEORGE B. NGUYEN  
SUPERVISORY PATENT EXAMINER